A STUDY OF THE ATTITUDES OF ADULTS ENROLLED IN A PREFERRED PROVIDER ORGANIZATION REGARDING GENERIC PRESCRIPTION MEDICATIONS

by

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ABSTRACT

There has been a dramatic increase in the number of managed care companies who offer prescription drug benefits to people in the United States in recent years. These companies often either mandate or encourage their members to accept generic medication when it is available. Although consumer opinions of generic drugs were studied by several groups right after the 1989 Food and Drug Administration scandal, little information is available to understand current consumer attitudes.

For this study, a questionnaire was mailed to 889 members of a national Preferred Provider Organization with prescription drug coverage. The information requested on the survey included demographics, general opinions of generic medications, opinions of the role pharmacists play in giving information and recommendations on generics, what financial incentives would be necessary for people to choose a generic medication, and consumer awareness of the generic drug scandal of 1989.

The usable response rate was 31% (275/889). Of the 275 respondents, 120 (43%) believed that generic medications were

as effective as the brand name medications and 87 (32%) were neutral. Seventy-two percent of respondents considered their pharmacist a valuable source of information about generics. One hundred thirty respondents (53%) would need to save five dollars or more to choose a generic medication over a brand name. When asked if they were aware of any publicity surrounding the generic drug industry in recent years, 132 respondents (48%) indicated that they were aware. Of these respondents, however, 76 people (58%) were either neutral or disagreed that the publicity they heard decreased their faith in generic medication.

In reviewing the results it appears that many consumers had forgotten the publicity about the generic drug scandal between the time it occurred in 1989 and the time they completed the survey in 1991 or they were never aware of the scandal. Apparently people have a significant trust in their pharmacist and are influenced by what their pharmacist says regarding generic medication. Managed care companies who want their members to select generic medication need to structure their prescription drug co-payments so that members save a minimum of five dollars when a generic is available. Overall, consumers appear trusting of both generic medication and their pharmacist's opinion regarding drug product selection.

Dedicated to my loyal and supportive wife, Colleen, and three wonderful children, Tania, Carmen, and Seth, who now have a father back.

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CHAPTER I

INTRODUCTION

Since the mid 1970s, when legislatures began repealing antisubstitution laws in each of the states, generic medications have taken a larger share of the prescription drug market. Managed care operations, which now represent a large segment of the health care market, have either encouraged or mandated the use of generic medication. Perri and colleagues reported that there has been a reluctance on the part of some consumers to use generic medications because of the Food and Drug Administration (FDA) and generic drug industry scandal of 1989.[1] This scenario may be placing the pharmacist in a difficult situation between health care programs that demand generic medications and those patients who do not feel comfortable using them.

A review of the medical literature regarding generic medication over the past 15 years indicates a continuing controversy over this issue.[2,3] Physicians have stated concerns over the possibility that the same medication from different manufacturers could cause different therapeutic responses in the patient. Other health care professionals respond that there have been no broad based reports of such problems. One important concern has always been the government's ability to function as a watchdog over the pharmaceutical industry. The generic drug scandal of 1989

and related publicity about the Food and Drug Administration (FDA) only served to further complicate the matter.

Studies that examined consumer attitudes of generic medications before the 1989 scandal showed conflicting opinions. Some researchers reported support for generic drugs, while others noted consumer skepticism.[4] Following the 1989 scandal there appeared to be a decline in consumer acceptance of generics and a fairly high awareness of FDA problems.[5]

Now that two years have elapsed and more recent reports have publicized improvements at the FDA and safety with generic drugs, there is confusion over current consumer attitudes. The number of health care programs that require generics to be substituted for brand name medications is increasing. It is imperative that the pharmacy community understands how consumers feel about generic medication, whether their attitude regarding generics was influenced by the generic drug scandal of 1989, and if consumers can be influenced by their pharmacist to accept generic medications.

Statement of the Problem

Prescription drug costs have been at the forefront of inflationary health care concerns in recent years. One of the solutions has been for managed care companies to encourage patients to use generic medications instead of brand names (those medications made by the innovator company

and which can cost considerably more money.) In fact, many plans mandate that generic medications must be dispensed. The generic drug scandal of 1989 complicated the situation because some consumers were apparently concerned about the quality and effectiveness of generic products. The pharmacist must adhere to third party program regulations in order to get paid for the prescriptions they fill, but they must also deal with the patient who might be reluctant to accept the substituted medication.

Objectives of this Study

Given the lack of information about current consumer knowledge of the generic drug scandal of 1989 and attitudes about generic medications, this study will examine the following issues: general attitudes of patients toward generic medications; the role the pharmacist plays in disseminating information to patients regarding generics and how that information is received; consumer attitudes about specific drug categories to determine whether opinions about generics are absolute or dependent upon the specific prescription or condition for which the medication is being used; and what kind of financial incentive consumers need to choose a generic medication over a brand name.

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CHAPTER II

LITERATURE REVIEW

Over the past 15 years generic medications have taken a larger share of the total prescription drug market in the United States.[1] Some people in this country have enjoyed lower prescription costs by accepting the generic version of the medication they take.[2] Many managed care operators and health insurance companies have either offered incentive programs that encourage the use of generics or have mandated their use altogether. Because more people each year have prescription drug benefits which encourage the use of generic medications, there is a potential conflict between the patient who wants a brand name medication and the pharmacist, who is trying to abide by program regulations. To understand consumers' attitudes regarding generics, a review of some of the historical, legislative, and clinical issues regarding prescription medication is necessary.

Early Federal Legislation

The legislative history of drug law in the United States greatly influenced the development of the generic drug industry. As early as 1831, federal statutes authorized the New York College of Pharmacy to supervise and regulate

the importation of drugs into this country. An 1848 federal law required examination of drugs and medicinal preparations in an attempt to prevent contaminated products from coming into the United States.[3] From 1848 through the end of the century, no other federal law regulated the manufacture, prescribing, or dispensing of medications. Although many bills were introduced in Congress between 1880 and 1906, none made it through the legislative process. Economic and regulatory conditions during this time favored small companies in the food and drug industries.[3] Because of this, small companies proliferated in wide geographic areas. The larger and more established companies had no advantage in terms of distribution because of high transportation costs and other factors. Antirebate and antitrust legislation also favored small companies. Even foreign companies had advantages which compromised large scale producers of food and medicines in the United States. All of these factors lead to a very competitive drug market where some operators cut corners in quality and safety to create better profit margins. Because of the large number of small companies that were spread out over a large geographic area, the government had a difficult time overseeing all of the operations.

Government agencies were receiving large numbers of complaints with regard to foods and medications that had poor quality or simply did not work. Advertising of the

early 1900s appealed to the emotional needs of Americans and implied products were of the highest quality and wholesomeness. The public was soon to hear of the abuse of confidences in which many of these companies were involved.

Although the government had heard reports of problems with purity in the food and drug market for years, it was not until 1906 that conditions became so publicly deplorable that regulation was inevitable. Harvey Wiley, Chief Chemist of the Department of Agriculture, had been reporting concerns about preservatives, additives, and contaminants in foods and drugs since 1880. In 1902 he stunned many readers with a series entitled "The Poison Squad" which correlated contaminants with "sickliness and unattractiveness."[3]

Finally, in December of 1905, President Theodore Roosevelt asked Congress to pass legislation to protect the American people from adulterated food, beverages, and medications. The Senate passed their version on February 21, 1906, and the House answered with their own on June 23rd.[3] By June 30th, only seven days later, the President had signed the compromise bill, which went into effect on January 1, 1907. The federal government had taken the first real step to regulate the drug industry in the United States by enacting the Pure Food and Drug Act of 1906. This act allowed the government to seize any mislabeled or adulterated medication.[3]

The Food, Drug, and Cosmetic Act of 1938

Although the Pure Food and Drug Act of 1906 accomplished a great deal in terms of protecting the public against contaminated medicinal products, there was no federal regulation regarding the active medicinal ingredients or the chemical bases which held them. This weakness was particularly important because advertising for medication was aimed almost exclusively at the consumer instead of the physician. Because nonnarcotic medication could be purchased without a prescription, consumers could choose medications themselves or ask their pharmacist for a recommendation. Five percent of the medication manufactured during this time was sold to the public by physicians and another 25% was sold through a pharmacy by prescription.[4] This left 70% of the medication to be purchased by consumer choice.

Sales of medicine in drug stores increased 600% in the 20 years between 1906 and 1926, mainly because of successful large scale advertising by manufacturers to the consumer.[4] Companies could essentially make whatever claims they desired about their products with little concern for government intervention. There was no federal statute that demanded that a company establish records of safety and efficacy for their products. The regulations of the early 1900s provided only some assurances that labeled ingredients matched actual product.

An incident occurred in 1938 that prompted additional legislation to better protect the public interest. A chemist who was working for the drug company, Massengill, was manufacturing sulfanilamide elixir. Instead of using the approved solvent, polypropylene glycol, he used diethylene glycol, which is better known as radiator antifreeze. The untested solvent was lethal and 107 children died before the problem was discovered.[5] The American public was outraged and Congress responded by passing the Federal Food, Drug, and Cosmetic Act of 1938. When President Roosevelt signed the bill into law, there were new regulations for pharmaceutical manufacturers to follow when manufacturing drug products. The public had better protection because these companies would have to show that a product had some record of safety before it could be marketed. The act essentially addressed product safety in two ways: first, all manufacturers of new products would be required to show documentation of safety before marketing and second, nonnarcotic medications would be categorized into prescription and over-the-counter categories. Narcotics had previously been changed to prescription-only status in 1914 by the Harrison Narcotic Act. The 1938 law, however, required that some nonnarcotic medications be available by prescription only. Although the distinction between prescription and over-the-counter products was loose until the Durham-Humphrey Amendment in 1951,

the guidelines were generally accepted.

The effect of the 1938 law was substantial as companies shifted their marketing efforts from the ultimate consumer to the physician. There were advantages for the larger pharmaceutical companies as the cost to document safety was somewhat prohibitive for the small pharmaceutical houses. Although this bill gave an added degree of safety to the consumers in this country, there was no regulation that addressed the issue of product efficacy.

The 1951 Durham-Humphrey Amendment

In 1951, the Durham-Humphrey Amendment specified the distinction between prescription and nonprescription medications. Drugs fell into one of three categories: narcotics, which were later classified as controlled substances, prescription medicines, and over-the-counter products. The distinction between these categories of drugs was determined by whether a drug could be used safely without physician supervision.

The Kefauver-Harris Amendment of 1962

It was not until 1962 that Congress enacted specific safety and efficacy guidelines for all pharmaceutical manufacturers. In 1962 the thalidomide scandal provided the impetus for this legislation. Thalidomide was available in Europe and was used as a sedative. Unfortunately, when pregnant women used this drug, it caused severe congenital

defects in their unborn children. Sufficient evidence to substantiate the problem came after hundreds of babies had been born with horrible anomalies.[6] In the United States, the problem was smaller because the medication had only been released to physicians who were trying it on a limited number of patients. Although the number of children born with defects was smaller in the United States, the public outcry was no less strong.

Congress, through Senators Kefauver and Harris, legislated a whole new process by which medications would be allowed on the market. The process required extensive clinical testing for both efficacy and safety.[7] The clinical testing required drug companies to perform randomized and well-documented clinical studies.

State Antisubstitution Laws

Other important trends occurred during the period of increasing federal legislation that prompted passage of significant state laws which would also impact the pharmaceutical industry for decades. There was a tremendous influx of new and important drug products just after World War II and into the 1950s.[8] In particular, physicians had new antibiotics available to treat infections and a new class of drugs called phenothiazines to treat mental illness. There were also tremendous opportunities for profits by the pharmaceutical companies who were granted 17

year patents on new medications.

The potential also existed for unscrupulous companies to make look-alike drugs and steal away some of the profits from the companies that had discovered them.[4] In some instances a few drug companies sold products that looked very similar to the innovator's product and supposedly contained the same active drug. A pharmacy could purchase such counterfeit products at a greatly reduced price, charge the patient as if it were the innovator product, and make much higher profits. Because of the potential for lost revenue by brand name companies, the Pharmaceutical Manufacturers Association (PMA) lobbied hard for specific legislation to protect them. The American Pharmaceutical Association (APhA) supported their efforts as did the American Medical Association (AMA).[4] Both groups were concerned about potential harm to patients who might receive inferior medication and the destabilizing effect the lost profits might have on the brand name manufacturers.

In the mid 1950s, after considerable efforts on the part of these three organizations, all states passed some form of antisubstitution legislation which gave complete power to the prescriber to choose the specific drug product. The pharmacist was required to dispense the exact brand name of drug written by the physician and could not substitute "look alike" or generic (same active ingredient) medication.

Changes in the 1960s Bring New Perspectives

The decade of the 1960s brought about several important changes in the medical arena. These changes ultimately affected the attitudes of legislators regarding the state antisubstitution laws. The first change was the perception within the medical community that the United States had a strong agency to oversee pharmaceutical manufacturers, the Food and Drug Administration (FDA). All available evidence suggested that this agency could uphold the public safety with regard to medication and also protect the rights of innovator companies. There was no longer a perceived threat of counterfeit medication robbing brand name companies of their legitimate profits.

Another factor that led to change in the 1960s was the strengthening of pharmaceutical education. Many people began to recognize the pharmacist as the best person to judge the quality and cost of prescription medication.[9]

Possibly the most important factor to change perspectives on the state antisubstitution laws was the passage of amendments, Title XVIII and Title XIX of the Social Security Act. Congress passed these two bills in 1965 and established Medicare (Title XVIII), a health care benefit for the elderly, and Medicaid (Title XIX), a health care plan for the poor.[10] Congress considered adding a government subsidized health insurance plan to the original Social Security Act of 1935, but the AMA opposed it and

plan never passed. Now with Medicare and Medicaid in place, the federal government accepted the idea that citizens of the United States who could not afford healthcare or who were aged, should have it provided to them.

When Title XVIII and Title XIX were passed in 1965, there was no clear cut analysis of what the programs would cost or how they would be funded in the long-term. While the programs themselves had great merit, no one in Congress predicted the cost overruns and budgeting problems these programs would create over the next 25 years.[11]

The constant and dramatic increases in health care inflation linked the Medicaid and Medicare legislation to the change in attitude regarding the antisubstitution laws. By 1970, it was obvious to Congress that changes were needed to control the dramatic escalation of medical bills. In 1972, the federal government established Peer Review Organizations (PRO) to examine the legitimacy of medical claims.[11] Senator Wallace Bennett of Utah was instrumental in sponsoring a bill that created the Professional Standards Review Organization (PSRO).[10] The PRO and PSRO were not formal organizations, but rather a formal structure to facilitate peer review. The intent of the legislation was to reduce expenditures by hospitals and physicians.

At the same time, the Department of Health, Education, and Welfare developed a new plan called Maximum Allowable Cost-Estimated Acquisition Cost (MAC-EAC). This program was

implemented in 1976 and set limits for reimbursement on some medications that were available from multiple sources (i.e., generic drugs). The stumbling block for the federal government was that state laws made it illegal for pharmacists to substitute one brand for another, without permission from the prescriber. Without legislative relief, the pharmacist was in a position of being reimbursed for a generic (multisource) drug according to MAC guidelines, while state laws would require that a brand name must be dispensed.

The answer appeared to be the repeal of the state anti-substitution laws. APhA reversed its stand from the 1950s and supported the repeal of these laws.[4] They saw an opportunity to expand the role of pharmacists by allowing them to choose the specific prescription drug product and at the same time save the federal government a considerable amount of money. The federal government saw this as a financial issue: brand name medications cost more than generic versions and bulging Medicaid and Medicare budgets could no longer afford to pay the difference.

Groups in the health care field had a different perspective. The AMA, PMA, and the National Association of Chain Drug Stores (NACDS) came out in opposition to the repeal of the state antisubstitution laws.[4] Strom and others classified the motives of these groups into four categories: economics, quality, physician prerogatives, and equivalency.

These issues will be discussed in detail later, but it is important to note that a controversy ensued that divided the pharmacy profession.[12]

In the end, federal officials received the support they needed and over a period of several years, all states repealed laws which prevented substitution by pharmacists.[4] The AMA gained one concession in that prescribers could prevent the substitution of medication if it was deemed medically necessary.

Officials at the Health Care Financing Administration (HCFA) were quick to insist that certain medications be dispensed in generic form (unless otherwise specified by the physician.) Although Medicaid is a shared program between the federal government and the states, the individual states administer it. The states had a choice whether to comply with the federal guidelines or not, but noncompliance meant no matching federal monies for the Medicaid program. Every state originally complied, but there has been movement on the part of some states to operate their own programs.

The Drug Price Competition Act of 1984

One last piece of legislation that had a substantial impact on the generic drug industry was passed in 1984. The Drug Price Competition and Patent Restoration Act was designed to facilitate the entry of generic medication into the market. Congress attempted to protect brand name

companies who were losing investments due to long approval times by the FDA.[12] Brand name companies welcomed the bill because there were some specific products whose 17 year patents were close to expiring by the time the FDA granted approval to market the medication. Some drugs, for example, took 15 years to gain FDA approval, which left only two years of noncompetitive marketing to recover research and development costs. The 1984 legislation allowed a minimum of five years of noncompetition for these drug products, no matter how much time the approval process required.

Generic manufacturers were also pleased with the legislation because it changed the approval process after a medication had lost its patent. Prior to this legislation, a company that desired to make the generic version of a drug had to submit all the safety and efficacy studies the innovator companies performed. This made a generic medication costly and the research redundant, since the brand name company had already shown the safety and efficacy of the product. The 1984 bill outlined an Abbreviated New Drug Application (ANDA), which required the generic manufacturer to show bioequivalence with the brand name product and good manufacturing procedures. These requirements were far less expensive than testing for safety and efficacy, which opened the door for smaller pharmaceutical companies to enter the more lucrative generic market.[13] Schwartz estimated the 1984 legislation expanded

the generic drug market by two billion dollars a year.[14]

Concerns About Substituting Generics For Brand Names

In the early years that pharmacists were allowed to substitute generic for brand name products, there was a surprising lack of interest on the part of many pharmacists to do so. Also, consumers were reluctant to take generics. Although state Medicaid programs mandated generic usage in some cases, this portion of prescription business was generally small. An analysis of drug substitution patterns in California in 1977 showed low generic usage (below 14%).[4] This trend continued on a national level. A study in 1985 showed that after 10 years of open substitution opportunities only 14.7% of all prescriptions were filled generically in the Unites States.[15]

Many hypotheses have been presented to explain these behaviors by pharmacists and consumers. Strom and his colleagues believed the lack of substitution was caused by concerns for equivalency, quality, and economic factors.[8]

Equivalency has triggered the greatest debate among health care officials because there are many ways to consider whether two products are equivalent. There are three basic definitions to examine when comparing pharmaceutical products with the same active ingredients: chemical equivalence, biological equivalence, and

therapeutic equivalence. [16-18]

Chemical (or pharmaceutical) equivalence is defined as two or more drug products that contain equal amounts of the same therapeutically active ingredients in the same dosage form. Biological equivalence (also called bioequivalence) is defined as two or more chemically equivalent drug products that produce comparable bioavailability characteristics in an individual when administered in the same dosage form. Essentially, this definition suggests comparing information such as how quickly each manufacturer's form of the same medication is absorbed into the blood stream and the maximum concentration each product achieves. Therapeutic equivalence is defined as two drug products that produce the same efficacy and/or toxicity.[8]

Many health care professionals were concerned that the equivalence issue was not properly regulated to insure that patients would receive the same therapeutic response from brand name and generic medications. In response to this concern, the FDA published regulations for bioequivalence in January 1977.[13] Because of the importance of these guidelines they are quoted below:

> (1) For drugs first approved after 1962 and for older drugs that may have bioequivalence problems, the generic product must be shown to have the same extent of bioavailability as the innovator's by an appropriate method that shows that the mean extent of absorption (area under the curve or AUC) will not differ from that of the innovator's product by more than 20 percent;

(2) the generic product must be shown to have the same rate of bioavailability as the innovator's by an appropriate method that shows the average maximum and minimum concentrations do not differ from those of the innovator's by more than 20 percent and that the times for the products to reach their maximum concentrations do not differ significantly. Statistical methods will then be applied to ensure that the generic product is not excessively variable from dose to dose within patients.
(3) For those drugs that cannot meet the statistical criteria due to inherent variability, the 75/75 rule shall apply. A test will show that at least 75 percent of the people tested do not show a variation of more than 25 percent between the innovator's and generic products. (In one chemical class of drugs, the psychotropic phenothiazines, this criteria shall be expanded to allow 70 percent of the people tested to show a variation of 30 percent or less between the two products.)

Debates still continued regarding the types of specific tests that should be done, the types of patients used in testing, and how often testing should be performed. Another concern was informing health care professionals when bioequivalence problems were detected. In answer to this concern, the FDA compiled a text, Approved Drug Products with Therapeutic Equivalence Evaluations (also called the Orange Book). This text is a listing of medications that are assigned to one of five classifications. These classifications are:

Class A : drug products for which there are no known or suspected bioequivalence problems.
Class B : drug products that the FDA does not consider therapeutically equivalent.
Class AB: drug products that require the manufacturer to submit bioavailability data to establish equivalency.
Class BX: drug products where there is insufficient data to establish equivalency.

Class AP: Injectable aqueous solutions where there are different routes of administration.

This book allows pharmacists to evaluate drug products to determine if any equivalence problem exists.[19] Although the Orange Book is a required test for all pharmacies in the United States, a study recently reported that many pharmacists have not been reading it.[20]

The FDA determined that not all generics could be considered equivalent to the brand names. Medications such as levothyroxine, theophylline, conjugated estrogens, thioridazine, phenytoin, and topical triamcinolone have documented equivalence problems.[21 26] Because some of these drugs had originally been "A" rated, some pharmacists had their fears substantiated that government approved generics can have equivalence problems. The end result of this was evident in the previously reported study where only 14.7% of prescriptions were being filled generically after 10 years of open substitution.

The second issue Strom raised which might have caused a reluctance on the part of pharmacists to substitute generics is continuous quality. This is a separate issue from equivalence because the manufacturer has to have the capability of reproducing the same product each time. In addition, pharmacists and others wondered if all generic companies had the funds, commitment, and ability to manufacture quality medications consistently. The health

care professions had to depend on the FDA to oversee the generic drug industry to insure that all companies complied with good manufacturing standards. Indeed, it was this very issue that led to a scandal in 1989 within the FDA and some generic companies. The following section examines this scandal in detail.

The third issue Strom raised was physician prerogative.[12] As previously stated,[12] the medical profession did not want to give up their right to choose the specific drug product. The AMA contended that physicians have a unique opportunity to evaluate a patient's response to prescribed medication.[18] Their contention was not that the pharmacist was unqualified, but rather that the pharmacist was not in a position to follow patients' lab work and physical examination to evaluate the medication's effectiveness.[18] Others argued that if a product was within bioequivalence standards, there should be no difference in therapeutic response. Many pharmacists were aware that specific physicians did not want their prescriptions substituted and that doing so could create animosity between themselves and the prescriber. This might have been a substantial factor in pharmacists substituting behavior.

Strom's final category was economics.[12] There were two monetary issues that impacted the amount of substitution that occurred. The first was the cost of added inventory that generics were causing. Because some people wanted

brand names and some people wanted generics, both products had to be stocked in the pharmacy. This cost pharmacists money as more inventory was required to be in stock.

The second monetary issue was more closely related to the patient than the pharmacist. A study of brand name and generic drug prices conducted in 1974 did indeed show a savings to the consumer.[2] Although prescription drug prices are a big issue now, in the 1970s prescriptions were considered affordable. This study showed price savings of one to two dollars per prescription (see Table 1). The prices listed in this table represent the price for the most commonly prescribed strength of medication and most commonly prescribed quantity. Many customers may have perceived too low of benefit to accept generics on a wide scale.

Although the pharmacist was engaged in continuing discussions and evaluations about substitution, the consumer was really not all that informed about this issue. Pharmacists have slowly been informing the public about the cost savings and the difference in price between brand name and generic products. It was not until 1989, however, that the national media gave considerable attention to generic medications.

The FDA and Generic Drug Scandal of 1989

The Drug Price Competition and Restoration Act of 1984 caused a dramatic increase in the number of ANDAs submitted

Table 1

Consumer Prices on Brand Name and Generic Prescription Medications in a 1974 Study*

Product	Lowest Generic	Lowest Brand	Mean Generic	Mean Brand
Tetracycline	2.36	2.40	3.80	5.04
Penicillin	1.88	2.36	3.40	4.96
Prednisone	1.60	1.60	3.30	3.50
Meprobamate	2.20	3.25	3.70	4.80
Reserpine	2.20	4.30	3.80	6.90
Digoxin	1.50	1.40	2.40	2.40
Chloral Hydrate	2.40	3.60	3.90	4.80

* Study conducted by A Gumbhir, PhD and C Rodowskas Jr., PhD. Reported in Am J Pub Health 1974;64(10):977-82.

to the FDA.[9] In addition to this increase in workload, Congress also passed more than 20 pieces of legislation which increased FDA responsibilities and required added inspections and application reviews.[1] At the same time, the federal government was becoming more sensitive about the growing federal deficit. In response to this, President Reagan was elected with a plan to reduce the budget by curtailing government spending. He responded by cutting budgets to government regulatory agencies, including the FDA.[1] From 1980 to 1989 the number of FDA employees performing non-AIDS related tasks declined 13% (Figure 1). This set of circumstances paved the way for an FDA and generic drug industry scandal that became public in 1989.

On July 11, 1988, Inspector General Investigators from the Department of Health and Human Services (HHS) appeared at the FDA and sealed off one of the offices. A comprehensive investigation ensued that lasted into early 1989. By late April 1989, reports began to surface outlining the payment of illegal gratuities to three mid-level FDA employees. Over the next six months, the pharmaceutical industry, medical professions, government and public were shocked to hear of irregularities at the FDA relating to fraudulent activities involving a small number of generic manufacturers. A synopsis of the findings of this and subsequent FDA investigations through 1989, as well as some of the reprimands, is reported here from a

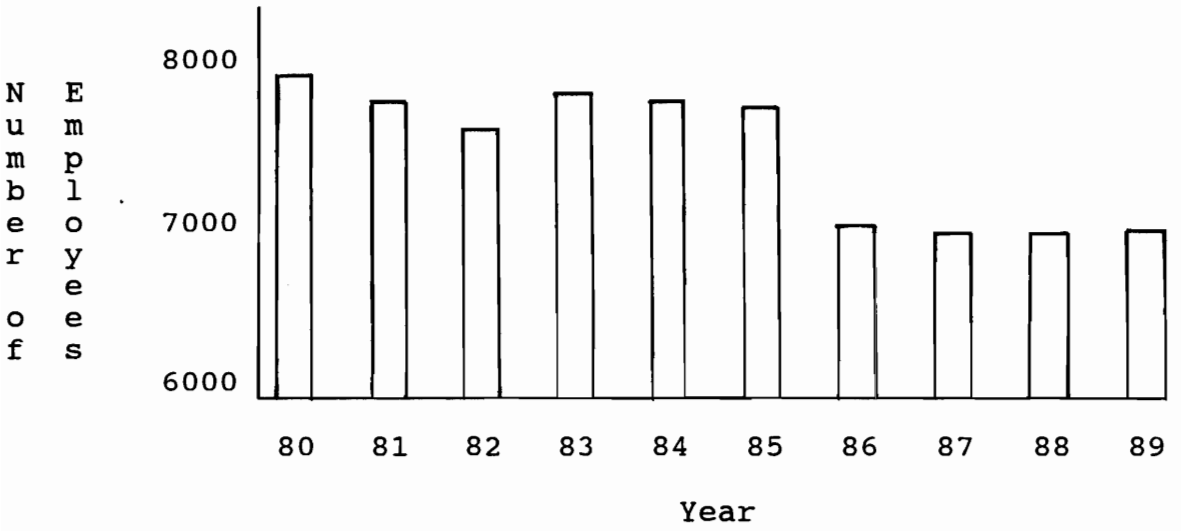

Figure 1

Number of FDA Employees Involved in Non-Aids Related Work From 1980 to 1989

presentation by Donald Hare, Special Assistant to the Director of Generic Drugs at the FDA.[28]

1. A vice-president of Pharmaceutical Basics (PBI) of Denver, Colorado, pled guilty to giving an unlawful gratuity to a former FDA supervisory chemist. Not directly related to these charges is the fact that this company had to recall fifty million doses of a drug, carbamazepine, used to prevent seizures, because of tablet dissolution problems. Reports indicated that 12 patients experienced seizures while on the generic drug. There were also 2 deaths reported while patients took the generic drug, however it was never determined if the seizures or deaths were associated with this product. The vice-president was convicted of criminal charges and was sentenced. The company received letters outlining violations of Good Manufacturing Practices.
2. Quantum Pharmics of Amityville, New York, which is owned by Wyeth-Ayerst Laboratories, a brand name firm, was found guilty of misrepresenting information to the FDA involving three generic products. The agency found that Quantam made false statements and omitted information related to the production and testing of medication for which they were making application to manufacture. The FDA moved to withdraw approval of 25 ANDAs. They also changed the rating for these products in the Orange Book from "AB" to "BX" which reflects the

FDA's inability to determine equivalency with this product. Wyeth-Ayerst informed the FDA that Quantum would suspend all operations.

3. Vitarine Pharmaceuticals of Springfield Gardens, New York, gave false information in their ANDAs for certain products. Vitarine submitted brand name Dyzaide, Calan SR, Proventil Repetabs, Inderal LA, and Medrol samples as its own generic versions for bioequivalence testing. The FDA moved to withdraw approval for 25 generic products which had to be removed from the market. In addition, the rating for the generic version of Dyazide was changed from "AB" to "BX".
4. Par Pharmaceuticals of Spring Valley, New York, was guilty of giving illegal gratuities to two FDA review chemists. The FDA also found that their generic version of Maxzide was not the same formulation as outlined in the ANDA. In addition, Par had falsified some production records. Because of these findings, the FDA withdrew Par's license to manufacture three generic products: triamterene/hydrochlorthiazide, orphenadrine/ acetaminophen, and valproic acid. The ratings for these drugs was changed in the Orange Book from "AB" to "BX".
5. Bolar Pharmaceuticals of Copiague, New York, submitted brand name Mellaril and Macrodantin instead of their generic product for bioequivalence testing. The firm eventually pled guilty to 20 criminal charges of

fraudulent generic drug applications. The FDA withdrew approval for all involved medication and a federal court eventually fined the company 10 million dollars.[29]

6. Barre-National of Baltimore, Maryland, had deficiencies in manufacturing procedures. They also withheld the results of some stability tests because of failures. The FDA demanded the recall of their hydrocortisone lotion and a theophylline syrup and initiated the suspension of distribution of 20 other products.
7. Sidmak Laboratories of East Hanover, New Jersey, was guilty of manufacturing a superpotent vitamin product. The testing facility, Quality Research Laboratories, had inaccurately tested and approved a product that contained 50 times the labeled quantity of vitamin D. Because vitamin D is a fat soluble vitamin and can cause toxicity in high doses, the FDA treated this as a serious health threat. The FDA recalled this product, as well as another product, phenytoin extended release capsules. This action was taken because of a lack of trust in the testing procedures for both products.
8. Superpharm of Bayshore, New York, was found to have submitted research and development records with irregularities and discrepancies involving six products. The FDA changed the ratings for diazepam and ibuprofen from "AB" to "BX" in the Orange Book.
9. American Therapeutics Incorporated (ATI) of Bohemia, New

York, was named in criminal action involving the payment of an illegal gratuity to an FDA chemist. Besides eventual fines that were levied, the FDA rescinded approval for their chlorzoxazone 500mg tablets and changed the ratings on their versions of prednisone, clonidine, and lorazepam form "AB" to "BX".

10. Pharmafair of Hauppague, New York, had a history of manufacturing problems. Their entire 1988 production of phenylephrine ophthalmic solution and numerous lots of nystatin suspension were recalled due to variation in potency.
11. Zenith Labs of North Vale, New Jersey, had minor problems with Good Manufacturing Practices (GMPs) at a plant in Puerto Rico. The plant had been placed on inactive status so no other action was taken.
12. The President of Quad Pharmaceuticals of Indianapolis, Indiana, conspired to pay illegal gratuities to three FDA chemists. Inspections of the facilities found no significant deficiencies. Criminal charges and fines were eventually levied against the president and company.
13. Watson Laboratories of Corona, California, had significant deficiencies in record keeping and operations. The FDA sent a "Ten Day Letter" demanding immediate compliance with these standards and regulations.

14. Chelsea Labs of West Hampstead, New York, produced the drugs verapamil, disopyramide, perphenazine/ amitriptyline, oxazepam, and plain perphenazine which all fell below regulatory standards. Chelsea received a "Ten Day Letter" demanding that the give the FDA information which would indicate that all problems had been solved.
15. The three chemists who worked for the FDA were fired, convicted of accepting illegal gratuities, and sentenced by the courts.

In August of 1989, the FDA began an extensive sampling and analysis program of the 30 most prescribed generic drugs and their brand name counterparts.[30] These products are listed in Table 2. Three hundred chemists performed 36,000 tests. The chemists found a total of 27 products (1.1%) to be outside the FDA specifications. This rate is comparable to that found in brand name medications.[28]

Extensive inspections were performed at hundreds of generic and brand name firms. The findings of these inspections have just been reported above. The majority of these inspections revealed no problems in ANDA or manufacturing practices. Many of the manufacturing problems they did find were of a routine nature that FDA deals with regularly.[28] Manufacturers paid the illegal gratuities to encourage the chemists to speed up the approval of the company's generic drugs. The inspections could not detect

Table 2

Top 30 Drugs Examined by the FDA
Following Generic Scandal

Rank	Name of Drug	Rank	Name of Drug
1	Amoxicillin	15	Diazepam
2	Penicillin	16	Phenobarbital
3	Ampicillin	17	Hydrocort Cr
4	Prednisone	18	Trimeth/Sulfa
5	Tetracycline	19	Dipyridamole
6	Hydrochlorthiazide	20	Nitroglycerin
7	Doxycycline	21	Nystatin
8	Ibuprofen	22	Triamcinolone Cr
9	Erythromycin Stearate	23	Propox Nap/APAP
10	Acetaminophen/Codiene	24	Lorazepam
11	Erythromycin Base	25	Imipramine
12	Cephalexin	26	Thyroxine
13	Amitriptyline	27	Metronidazole
14	Furosemide	28	Meclizine
15	Allopurinol	30	Ferrous sulfate

that any fast tracking actually occurred.

During the last six months of 1989 and first few months of 1990, the public and medical community were exposed to numerous headline stories in all forms of media which reported on the findings of fraud and corruption in the FDA and generic drug industry. Many of the reports were accurate, but some sensationalized the problem, suggesting more widespread irregularities than actually existed. The following reports are examples of what pharmacists, physicians, and consumers were reading.

From the Wall Street Journal[31]

> In its first crackdown on generic drug companies involved in fraudulent activities, the Food and Drug Administration revoked recent approvals granted to Par Pharmaceutical Inc. and American Therapeutics Inc..... FDA Commissioner Frank E. Young emphasized that if the generic drug scandal worsens "there is a real possibility" that the industry "may be totally discredited." He added that unless the agency moves swiftly "to safeguard the generic drug review system, the potential for a loss in public trust in generic drugs may be realized."

From USA TODAY[32]

> An expert panel of the American Academy of Family Physicians next month will urge the nation's 60,000 family doctors to stop prescribing generic drugs for some patients.... The committee's findings come in the wake of a credibility crisis already faced by the generic drug industry involving illegal payoffs to Food and Drug Administration scientists.... The Congressional Subcommittee Chairman, Rep. John Dingell, D-Mich. told Congress last month "the reality is the (approval) system does not work. Even without the payoffs, the system was characterized by arbitrariness and lack of procedures and standards."

From the Deseret News[33]

> The title of this article was "Danger Cited To Users of Generics."
>
> The Utah Pharmaceutical Association has issued a warning to users of Dyazide and Dilantin to immediately stop use of potential dangerous generic forms of the drugs in favor of established brand-names.... An attorney for Bolar (Labs) recently disclosed to the FDA that an internal investigation revealed that documents used to gain FDA approval apparently had been falsified.... Bolar is under criminal investigation for applications it submitted for several drugs including its generic version of Dyazide....Bolar informed the federal Food and Drug Administration that it could not be sure the products were therapeutically interchangeable with the brand-name counterparts.

Exactly how much of an impact these news stories had on consumers has been studied by researchers around the country. Gallup conducted a nationwide poll asking opinions of generics in the Fall of 1989. The results of this poll indicated a high awareness of the FDA scandal and 77% of those polled had changed their opinion of generic medication in general.[34] Perri and others studied consumer attitudes regarding generic drugs and found confidence had deteriorated from studies done before the 1989 scandal.[35] The amount of rhetoric pharmacists received regarding the investigation was much higher than that seen in the general media. Almost all of the professional journals and pharmacy newsletters have continued to report new information regarding generic drugs and the effectiveness of the FDA.[36,37,38]

Managed Care: A Solution for the 1990s

One last factor is important to understand the entire generic drug issue. This factor is the increasing number of insurance companies who pay for prescription medication but mandate the use of generic drugs. This situation might be causing conflicts with some pharmacists who are concerned about equivalency and quality, but who must dispense generics to follow third party guidelines. It might also be causing a conflict between patients who do not trust generics and pharmacists who must dispense them to be reimbursed appropriately by the insurance company. To understand how the generic guidelines developed, it is important to review the evolution of third party payers in the United States.

As the cost of medical care began to inflate dramatically in the late 1960s and early 1970s everyone looked for ways to control these costs. Instead of simply paying medical bills as they accumulated, the government and other third party payers wanted to control the utilization of medical care prospectively. One answer seemed to be Health Maintenance Organizations (HMOs). Federal legislation nurtured HMOs in 1974 when the government elected to subsidize these fledgling companies in hopes they would better control medical costs in the Unites States. Over the years, hybrid organizations have developed with new formats to attract different segments of the medical care market.

Under the general title of managed care operators, there are now a variety of organizations which include: staff model HMOs, Independent Practice Associations (IPAs), Preferred Provider Organizations (PPOs), Pharmaceutical Services Administrative Organizations (PSAOs), as well as the traditional indemnity carriers. The ability of each of these companies to manage medical costs is different as is the level of medical care which they offer.

The Staff Model HMO

This type of organization operates its own clinics and hires its own medical practitioners including physicians, dentists, nurses, and pharmacists.[39] Patients must go to one of the HMO's own clinics for medical treatment or to get a prescription filled. There is generally tight control over the physician's prescribing habits because the practitioner works directly for the HMO. The pharmacies in staff model HMOs operate formularies which cut down on investments in drug inventories. In many cases a patient would not be able to get a brand name medication if it were available from multiple sources because the product would not be stocked in the pharmacy. Patients who choose to use HMOs might have to accept the fact that they will be given generic medications or they must use outside pharmacies to purchase the brand name at their own expense.

Independent Practice Association (IPA)

Many staff model HMOs also operate IPA models as well. In this program the managed care company contracts with providers in independent practice to provide certain kinds of care.[39] Patients may use one of the physicians or pharmacies who are under contract for these services. Control over the physician's prescribing practices is good, but not nearly as strong as that exercised by the staff model because the practitioners are not full-time employees of the company. On the other hand, IPAs usually generate enough of a patient base that physicians want to remain in good standing with these companies. The whole purpose of a practitioner in private practice contracting with an IPA is to increase their patient base. With all of the HMOs and PPOs in the health care system, many physicians are losing patients to programs they are not contracted to take. There may or may not be a formulary with the IPA model, but generics are usually mandated. In most cases with an IPA there is a financial incentive for the patient to use generic medications and some financial penalty if brand names are used.

Preferred Provider Organization (PPO)

The Preferred Provider Organization is a loosely structured network of providers that perform various medical services.[40] The concept is to contract with a limited

number of providers for services and ask them for a very competitive reimbursement rate in return for large numbers of members. Unlike HMOs there is typically no formulary with these programs because the control over the prescriber is very limited. Most of these plans, however, offer financial incentives for the patient to accept generic medications and an increasing number of the plans are mandating them.

Pharmacy Services Administrative Organization (PSAO)

The PSAO concept became popular in the 1980s as the independent pharmacies' answer to the PPO networks. Because many companies were negotiating with chain pharmacies for PPO contracts, the independents were losing their customer bases.[41] Their response was to form groups that could purchase pharmaceutical products together at a better discount and to contract with third party plans. The PSAO fills an administrative function only by negotiating contracts on behalf of independent pharmacies and acting as an intermediary to the plan and the stores. The organization has no control over the physician's prescribing habits and although generics are encouraged, they usually are not mandated. This is usually an issue for the specific third party plan and has little to do with the PSAO itself.

Indemnity Programs

This kind of program allows the patient to see any physician or pharmacy they choose. These plans offer little incentive for the patient to choose a provider who will closely monitor medical costs. When a patient has a prescription filled, they pay the full cash price at the time of purchase. After submitting their receipt, the insurance company reimburses them for the purchase. The only way this kind of program controls cost is by requiring the patient to pay for the medical treatment at the time of service. Patients are less likely to pay the full price of a prescription they do not really need. Generics are encouraged by these plans, and financially, patients would save money if they used them. The problem is that people know they will be reimbursed a high percentage of the price anyway, so they will use whichever product they desire.

Each year the managed care companies take a larger share of the prescription drug market.[41] This has had a dramatic impact on the practice of pharmacy as a whole, but for the purposes of this study, it is important to note how this has affected drug product selection. The market share for generic medications was only 2% in 1982. In 1989 it was 33.1% (Figure 2). Managed care programs that mandated the use of generic medication caused much of this increase.

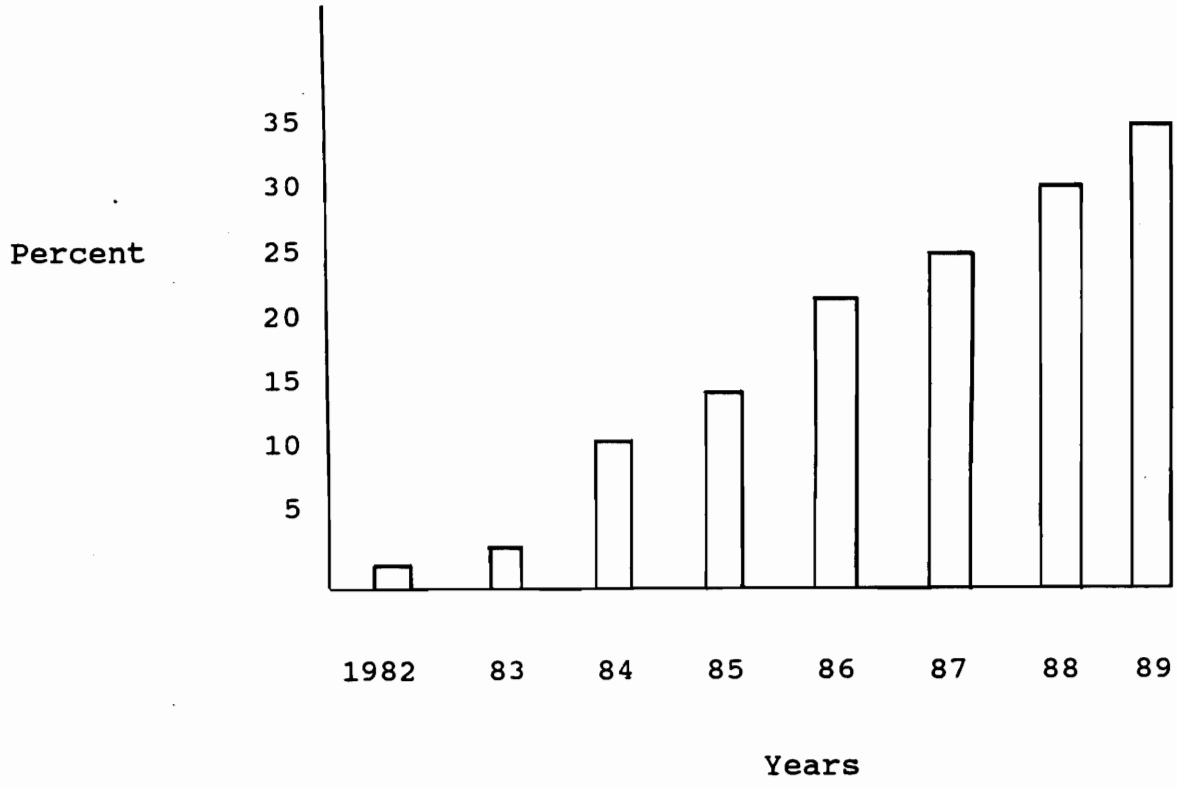

Figure 2

Percent of New Prescriptions Filled Generically By Year

Summary

Literature reports indicate that pharmacists and the public may be unwilling to promote or accept generic medications. The research and information presented would indicate that the low generic usage might be related to any of the following:

1. Physicians who do not maintain a high level of confidence in generics want their patients to receive brand names to prevent variable concentrations of medication in the blood. Therefore, they write Dispense as Written (DAW) on the prescription to prevent the pharmacist from substituting.
2. Pharmacists who are concerned about issues of bioequivalence and quality do not promote the use of generic medication.
3. Pharmacists may not be willing to save a person money on a generic medication at the risk of a customer complaint involving a generic product, so they do not promote them.
4. Consumers, having heard the publicity surrounding the FDA scandal want to purchase only brand name products.
5. Consumers, having had their physician or pharmacist tell them generic medications might not be equivalent to brand names, decide to avoid generic products. Now that managed care firms are mandating the use of generics, there might be some conflicts as described earlier.

Either the pharmacist has no confidence in generic medications, but must use them to comply with third party regulations or the patient may be required to use generics when they would feel more confident with the brand names.

This set of potential conflicts encourage study into contemporary consumer attitudes regarding generic medications and the patient's trust in the pharmacist's judgement about them. Therefore, the objectives of this study are to (i) assess the current knowledge consumers have about the generic drug scandal of 1989, (ii) investigate the level of confidence consumers have in generic medications, and (iii) study the level of trust people have in their pharmacist with regard to receiving information about generic medications.

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CHAPTER III

METHODOLOGY

Description of Sample

Because consumers with prescription benefit coverage offer more potential for conflict with the pharmacist over the use of generic medication, the investigator determined that this group should act as the study population. Therefore, a Preferred Provider Organization (PPO) in Salt Lake City was selected for this study. ScripCard Inc. has a total enrollment of just over 63,000 families and was willing to allow their members to be surveyed. ScripCard offers an incentive to members who accept a generic medication, but generic usage is not mandatory. ScripCard has over 100 plans in 15 states. The plan designs are typical for PPOs and the demographics of the members are diverse.

One plan was selected at random that enrolled 889 members in five different states. There was nothing outstanding or atypical about the plan chosen. A questionnaire and a letter from the president of ScripCard expressing support for the study were mailed to every member in the selected group with a prepaid return envelope (see Appendix). ScripCard's cover letter suggested to the members that answers to the survey could influence future

decisions regarding the use of generic medication by the PPO.

Surveys were mailed directly to selected members in a ScripCard company envelope. Each survey was stamped with a serial number so that if a second mailing was to be done, the respondents who mailed surveys back could be identified. The surveys were mailed out January 28, 1991 and respondents were asked to return the surveys by March 1, 1991.

Questionnaire Description

The questionnaire began with some questions regarding ScripCard benefits and services. An analysis of the responses to these questions, however, will not be included in this text, because the responses are not directly related to the topic which this study was intended to examine.

An introductory paragraph was included at the beginning of the survey form. The intent of this paragraph was to give each respondent a definition of the words "generic medication" to alleviate any confusion and provide instructions on how to answer the survey questions.

There were four different issues addressed in the survey which all related to generic medication. The issues were (i) the respondent's opinion of generic drugs, (ii) the respondent's opinion of their pharmacist, (III) whether the respondent was aware of the generic drug scandal of 1989, and (iv) demographic information regarding the respondent.

The questionnaire contained a set of statements about

generic medications which the respondents were asked to rate in the following manner: strongly disagree, disagree, neutral, agree, or strongly agree. In order to deter personal prejudice, half of the statements were stated from a negative perspective about generics and the other half were stated in a positive manner.

In terms of the respondent's opinion about generic drugs, there were some key features in the questionnaire that previous researchers had not included in their studies. A number of questions asked whether respondents had actually tried generic medications or if their opinions were formed by information from other people. Other questions related to whether the respondent's opinions were absolute or variable, depending on the type of medication. Three different kinds of medication were specifically addressed in these questions: chronic medications for serious diseases such as hypertension, diabetes, or cancer; medications for symptomatic relief such as coughing, pain, or cramping; or medications for birth control. The final question asked how large a price differential must exist between the brand name and generic products for the respondent to choose the generic.

In terms of the pharmacist, the key question asked whether respondents trusted their pharmacist. If their pharmacist expressed an opinion of generic medication to a patient, would that patient trust the pharmacist

sufficiently to alter their purchasing habits?

Demographic information was requested of respondents to allow examination of the relationship between selected variables and opinions about generic medication. Demographic variables collected were age, sex, level of education, and level of income.

Data Analysis

Descriptive statistics, such as frequency distributions were utilized for analysis and to summarize the data. Spearman Rank Correlation Coefficients were calculated to determine the extent to which relationships existed between selected variables.

CHAPTER IV

RESULTS

Response Rate

Of the 889 surveys that were mailed, 285 (32%) were returned with some form of response. Only three (.3%) were returned because of incorrect addresses. Two of the respondents (.2%) returned blank surveys (one reported no medication use and one no longer received Scrip Card benefits.) Eight of the respondents 9.9%) answered only one side of the questionnaire, so their responses are not included in the results. This left 275 completed surveys which represents a usable response rate of 31%.

Demographic Description of Respondents

Of the 275 respondents, 211 (78.1%) were female, 59 (21.9%) were male, and 5 did not indicate gender. There was a wide distribution of ages (Table 3) with the highest number of responders being in the category of 21 to 30 years. The other categories were fairly evenly distributed.

The distribution of respondents by educational level is listed in Table 4. Forty-two percent (113/269) of all respondents listed "attended college" as their highest achieved educational level. The next highest response was from those who graduated from high school.

Table 3

Respondent Distribution by Age

Age Group	Number of Respondents (%)
21 - 30 years	71 (26.2)
31 - 40	56 (20.6)
41 - 50	48 (17.7)
51 - 60	53 (19.6)
61 and over	43 (15.9)
Total	271 (100)

* missing four responses

Table 4

Respondent Distribution by Educational Level

Level of Education	Number of Respondents	(%)
Attended High School	13	(4.8)
Graduated from High School	72	(26.8)
Attended College	113	(42.0)
Graduated from College	57	(21.2)
Attended Graduate School	14	(5.2)
Total	269	(100)

* missing six responses

Respondents' distribution of annual family income is listed in Table 5. The greatest number of those surveyed, 73 (28.9%), reportedly made between $15,001 and $25,000. The next highest response rate, 53 (20.9%), came from those reportedly making under $15,000 per year. As the categories of income represented higher salaries, the number of respondents got smaller.

Respondent's Opinions About Generic Medication

In Table 6, the responses to questions regarding opinions of generic medication are reported. Forty-five percent (120/266) agreed with the statement, "In my opinion generic medications are as effective as brand name medications." The next highest response, 87 (31.9%), came from the neutral category. Only 65 people (23.8%) disagreed with the statement; however, the mean response was neutral (3.22 ± 1.05).

When the statement read, "I have actually used generic medications and have been satisfied with the results", there were 145 respondents (53.9%) who agreed. There were only 49 (18.3%) who disagreed. Because the number of neutral respondents was significant, the mean was $3.48 \pm .84$. This would indicate a neutral to slightly positive response.

When given the statement, "I trust the FDA (Food and Drug Administration). If generic medications pass FDA standards, they must be as good as brand name medications," 45% (123/273) of respondents agreed. Again, there were a

Table 5

Respondents Distribution by Income Level

Level of Income	Number of Respondents (%)
0 - $15,000	53 (20.9)
15,001 - 25,000	73 (28.9)
25,001 - 35,000	44 (17.4)
35,001 - 45,000	39 (15.4)
45,001 - 55,000	23 (9.1)
55,001 and over	21 (8.3)
Total	253 (100)

* missing 22 responses

Table 6

Responses to Questions About Opinions of Generics

Statements	Responses N (%)				
	SD	D	N	A	SA
Generics are as effective as the brand names.	19 (6.9)	46 (16.9)	87 (31.9)	95 (34.9)	25 (9.2)
I have tried generics and was satisfied with them.	23 (8.5)	26 (9.7)	75 (27.9)	113 (42.0)	32 (11.9)
If generics pass FDA standards, they must be as good.	21 (7.7)	48 (17.6)	81 (29.7)	96 (35.1)	27 (9.9)
I usually ask if a generic is available.	40 (14.7)	60 (22.0)	93 (34.2)	59 (21.7)	20 (7.4)

SD = Strongly Disagree
D = Disagree
N = Neutral
A = Agree
SD = Strongly Agree

large number of neutral responses which brought the mean to 3.22 ± 1.08).

The last statement about generics indicated that the respondent usually asked if a generic was available. The highest response, 93 (34.2%), was neutral. The other responses were evenly distributed giving an overall slightly negative mean of 2.84 ± 1.14.

Respondent's Opinions About Their Pharmacist

Table 7 shows the results of the two statements regarding the respondents' opinion of their pharmacists. The first statement in this table indicates that respondents reportedly value their pharmacists as a source of information about generic medication. The majority of respondents, 195 (71.9%), agreed. Only 19 respondents (7%) gave a negative response. The mean response was more positive at 3.93 ±.923.

The second statement was made to see what influence the pharmacist has in the decision of choosing a generic medication. The statement was, "If the pharmacist asked me if I wanted to buy a generic medication in order to save money, I would do it." The statement did not indicate the pharmacist had explained anything about the generic product. It only stated that the pharmacist asked if a generic was desired. The data indicate 59.4% of the respondents would purchase the generic just because they were asked. There were a fairly high number of respondents,

Table 7

Responses to Questions About Generics and Pharmacists

Statements	Responses N (%)				
	SD	D	N	A	SA
My pharmacist is an important source of information to me about generic medication.	4 (1.5)	15 (5.5)	57 (21.0)	115 (42.4)	80 (29.5)
If my pharmacist asked me if I wanted a generic ...I would purchase one.	16 (5.8)	32 (11.7)	63 (23.0)	102 (37.2)	61 (22.2)

SD = Strongly Disagree
D = Disagree
N = Neutral
A = Agree
SA = Strongly Agree

63 (23%), who were neutral. The mean response was neutral to slightly positive at 3.58 ± 1.13.

Respondents' Opinions of Discretionary Generic Substitution

Table 8 also shows the data on statements regarding specific categories of medication. These statements were used to determine if people's opinions of generics are absolute or dependent on the type of medication. When the medication is used for a condition such as diabetes, high blood pressure or cancer, only 55 (20.1%) of the respondents would use the generic product. The statement was made in a negative form. This indicates that the mean of 3.57 ± 1.22 is a statement of some agreement that these respondents would choose the brand name product for these conditions.

The second category of medication studied was that for symptomatic relief of coughs, pain, or cramping. A much higher number of people, 129 (47%), indicated they would take the generic drug. Again the statement was made in a negative way so that the mean of 2.70 ± 1.07 shows some support for the generic product.

The final category of medication examined was preventive drugs such as birth control pills. Only 64 respondents (24.7%) would purchase the generic product. The mean was overall neutral at 3.23 ± 1.18 given a negative statement on generics for preventive products.

Table 8

Responses to Questions About Generics and Medical Conditions

Statements	Responses N (%)				
	SD	D	N	A	SA
I would not buy a generic for diabetes, HBP, or cancer.	15 (5.5)	40 (14.6)	74 (27.0)	63 (23.0)	82 (29.9)
I would not buy a generic for pain, cramping, or coughing.	30 (10.9)	99 (36.1)	89 (32.5)	34 (12.4)	22 (8.0)
I would not buy a generic for birth control pills.	22 (8.5)	42 (16.2)	100 (38.6)	44 (17.0)	51 (19.7)

SD = Strongly Disagree
D = Disagree
N = Neutral
A = Agree
SA = Strongly Agree

Finally respondents were asked to indicate how much money they would need to save in order to purchase a generic rather than a brand name. The statement read, "In order for me to choose a generic, I would need to save $___." The greatest number of respondents, 130 (52.6%) indicated they would need to save $5.00 or more. The remaining responses were quite evenly distributed with 82 (31.7%) in the $3.00 to $4.00 range and 44 (15.7%) in the $1.00 to $2.00 categories.

Respondent's Knowledge of the Generic Drug Scandal of 1989

The question that intended to examine the consumer's knowledge of the generic drug scandal of 1989 was asked in this manner, "Have you heard of any publicity regarding generic medication in the past few years?" This was a simple yes or no question and the responses were quite even with 132 (48%) answering "yes" and 143 (52%) answering "no".

If the respondents answered "no" to this question, they were asked to skip to the demographic questions. If they answered "yes" to the question about publicity they were asked to complete the next nine statements. These statements were intended to determine what kind of publicity the respondent had heard. Table 9 displays the results of these statements.

With regard to decreasing the respondent's faith in the FDA, the highest response was in the neutral category with

Table 9

Responses to the Questions Regarding the Publicity Surrounding Generics

Statements	Responses N (%)				
	SD	D	N	A	SA
The publicity I am familiar with decreased my faith in the FDA.	7 (5.4)	23 (20.5)	55 (42.3)	35 (26.9)	10 (7.7)
The publicity decreased my faith in generic medications.	8 (6.1)	27 (20.5)	41 (31.1)	47 (35.6)	9 (6.7)
More recent publicity has been more favorable to the FDA and generics.	4 (3.0)	27 (20.8)	50 (38.5)	45 (34.7)	4 (3.0)
Irregularities were found at the FDA and with some generics- but now they are as safe as ever.	11 (8.5)	21 (16.3)	54 (41.9)	39 (30.2)	4 (3.1)
When I first heard the publicity, I asked my pharmacist to explain.	16 (12.8)	17 (13.6)	59 (47.2)	25 (20.0)	8 (6.4)
Today I trust the FDA and their ability to regulate generics.	8 (6.2)	26 (20.2)	51 (39.5)	34 (26.4)	10 (7.7)

SD = Strongly Disagree
D = Disagree
N = Neutral
A = Agree
SA = Strongly Agree

55 (42.3%). Forty-five respondents (34.6%) indicated their faith in the FDA was decreased. The overall response rate was neutral at 3.13 ±.97.

The next statement indicated that publicity decreased the respondent's faith in generic medication. There were 56 people (42.3%) who agreed with this statement. A significant number, 41 (31.1%), were neutral. This caused the overall rate of response to be neutral at 3.16 ±1.03.

A similar response was noted in statement 19, which indicated recent publicity had been more favorable to generic medication and the FDA. Forty-nine respondents (37.7%) agreed and 50 (38.5%) were neutral. The overall response was neutral at 3.13 ±.88.

The next statement was positive about generic medication, indicating that although irregularities existed in the past, generic medications were safe today. The responses were evenly distributed between agreeing, neutral and disagreeing. The highest response, 54 (41.8%), was neutral as was the overall response mean of 3.03 ±.96.

Next, the investigator wanted to determine whether the respondents went to their pharmacists to ask them about the publicity regarding generic medication. The highest response rate came in the neutral category with 59 (47%). The remaining respondents were evenly split between agreeing and disagreeing, bringing the overall response to a neutral 2.93 ±1.05.

Statement 22 was a restatement of question 8 regarding trust in the FDA. If answered in the affirmative, the respondent trusted the FDA's ability to regulate the generic drug industry. The greatest number of respondents, 51 (39.5%), were neutral and a few more people agreed than disagreed. The overall rate of response, again, was neutral at 3.09 $\pm$ 1.01.

The next statement was made in a negative form about generic medication. It stated that while the respondent may have heard some positive things about the FDA, they still felt uneasy about taking generic medication. More people, 55 (42.9%), agreed with this statement than disagreed, but a large number were neutral. This made the overall response neutral at 3.23 $\pm$ 1.08.

Statement 24 reexamined the trust people have in their pharmacist. If their pharmacist told them a generic medication might not be as effective as the brand name, would they stick with the brand name? The responses to this statement were skewed in favor of the pharmacist. One hundred sixteen respondents (89.1%) would trust their pharmacists and purchase the brand name product. The overall response was a very positive 4.29 $\pm$.77.

The final question was a restatement of an earlier one. In a positive way it stated the respondent feels more confident in generic medication than ever before. Most respondents, 60 (45.9%), were neutral on this statement.

Those agreeing and disagreeing were evenly distributed, which made the overall response rate a neutral, 2.95 $\pm$ 2.17.

Spearman Rank Correlation Analysis

The Spearman Rank Correlation Coefficient (r) is used with ordered or ranked data to determine the extent to which a relationship exists between two variables. In this survey, for example, the investigator wanted to determine how closely related a respondent's opinion regarding generics was to their age, sex, level of income, and level of education. In addition, Spearman r's were calculated for similar questions to examine the relationship between related questions. Overall, the results were statistically significant and a Spearman r of 0 to 0.4 would be considered either no correlation or a weak one. Values from 0.4 to 0.6 would be considered a moderate correlation and 0.6 to 1.0 would be considered a strong one. A negative value indicates an inverse correlation (i.e., as people get older they would be less likely to know about the generic scandal.)

Table 10 lists the Spearman Rank Correlation Coefficients for the demographic information (age, sex, level of income, and level of education) and five other variables (i) opinion of generic effectiveness, (ii) trust in the FDA, (iii) the importance of the pharmacists for information on generics, (iv) the amount of money a person would need to save to purchase the generic, and (v)

Table 10

Spearman Rank Correlation Coefficients

Statements	Variables			
	Age	Education	Income	Sex
Generics are as effective as the brand names.	-0.202*	-0.0174	-0.0401	-0.093
If generics pass FDA standards, they must be as good.	-0.111	0.0051	-0.0468	-0.062
My pharmacist is an important source of information to me about generics.	0.035	-0.035	-0.0313	0.002
For me to choose a generic I would need to save $_____.	0.118	-0.0122	-0.0481	-0.007
Have you heard any publicity about generic drugs in the past few years?	-0.081	-0.0389	-0.086	-0.072

* $p < 0.01$

knowledge of publicity about generic medications.

Reviewing the data on age and the four corresponding statements, there was only one correlation of significance. There was a weak negative correlation ($r = -0.202$) between people's ages and their opinion of the effectiveness of generics. This would indicate that the older people get, the less likely they would be to trust generics. It must be remembered, however, that this is a weak relationship. In examining the other demographic variables, sex, level of income, and level of education, there were no correlations of any significance.

The most important correlation examined was between the statement on the respondents' opinion of generic effectiveness and their knowledge of the generic drug scandal. If there were a strong negative correlation, that is respondents who heard publicity about generics also indicated they did not believe they were as effective, it could be argued that the drug scandal of 1989 was still having an impact on public opinion. In this study, no correlation between these two statements could be established ($r = 0.15$, $p = 0.014$).

Spearman r values were also calculated for a number of other related questions. The data showed that relationships could not be established for many of the statements; however a few questions had weak correlations. The Spearman r and P values are listed for these statements in Table 11. In each

Table 11

Spearman Rank Correlation Coefficients Comparing Other Questions to the Statement - I Usually Ask If a Generic Is Available

Statements/Variables	Spearman r	p value
In order for me to choose a generic I would need to save $_____.	-0.302	< 0.01
In general, I would NOT buy a generic medication for a preventive purpose such as birth control pills.	-0.287	< 0.01
In general, I would NOT buy a generic medication for a condition such as pain, cramping, or coughing.	-0.299	< 0.01
In general, I would NOT buy a generic medication for a condition such as diabetes, HBP, or cancer.	-0.378	< 0.01

case, the responses to the statement, "I usually ask if a generic is available" were compared to other questions. There was a weak negative correlation between this question and the statement, "I would need to save $____ in order to choose a generic." This indicates that those people who usually ask if the generic is available are more likely to accept the generic for less money.

There was also a weak negative correlation between the generic availability statement and "I would not accept the generic for preventive medications." These data indicate that people who ask if a generic is available are more likely to accept the generic for preventive drugs.

The same results were seen when comparing those people who ask if a generic is available and those who would not choose a generic for a medication which treated the symptoms of a cough, pain or cramping. The weak negative correlation indicates that the people who ask if a generic is available are also more likely to take a medication for symptomatic relief.

The final comparison listed in Table 11 examines the results of the statement on generic availability and using generic medications for a serious disease such as diabetes, hypertension, or cancer. The weak negative correlation indicated that people who ask if the generic is available are more likely to take the generic product for serious diseases.

CHAPTER V

DISCUSSION AND CONCLUSIONS

Demographics

The respondents to this survey were predominantly female with average annual incomes between $15,000 and $25,000. The vast majority of respondents were high school graduates and many had attended college. The survey was answered mainly by working women with incomes in the lower average range.

Knowledge of Generic Drug Scandal of 1989

The Wolfgang et al. study[1] and Gallup Poll survey[2] indicated a fairly high awareness of the generic industry scandal of 1989. Not only were people aware of the FDA and generic industry problems, there was a generalized decrease of faith in both. In contrast to these studies, only 48% (132/275) of the respondents were aware of any publicity surrounding generics. In addition, only 56 respondents (20.3% of total) agreed that the publicity decreased their faith in generic medications and fewer people, 45 (16.3% of total), had their faith decreased in the FDA. The high neutral responses to this statement are most interesting. If these respondents were truly aware of the publicity surrounding the 1989 generic drug scandal, it would seem

unlikely that they would not have an opinion regarding their faith in generic medications. It is possible that these respondents remembered hearing some news about generics a few years ago, but no longer remember what the substance of that news was. It is also possible that they heard the publicity about the scandal, but the impact of that information was not sufficient to change their opinion of the FDA and generic medications. More study would be required to substantiate this information, but the present survey would indicate that many people have forgotten the generic drug scandal of 1989 or the impact of the publicity surrounding that scandal has been diminished.

Both the Wolfgang study and Gallup Poll survey indicated an increased sensitivity to feelings about generic drugs by many people.[1,2] It is likely that many pharmacists were told "no" when they asked people if they wanted a generic instead of the brand name. Some pharmacists could have become sensitized over a period of time to the negative responses to questioning people about their preference of generic or brand name. It is possible that some pharmacists have quit asking people if they want a generic because of previous negative responses. If this has happened, it would appear that pharmacists are being too sensitive. According to this survey, 59% of responders would accept a generic, if the pharmacist simply asked them. Another 23% were neutral, which would indicate some

consideration would be given if a generic were offered. More study is needed, but indications from the present survey would suggest a more open-minded posture toward generic medications. This information could be significant as many plans encourage the use of generic medications. Pharmacists should not hesitate approaching patients about using the generic version. This survey indicates that many people would accept the idea.

Opinions of the Pharmacist

As reported earlier, the pharmacist has enjoyed a respected position with the public.[3] The present survey supports this premise as 71.9% of respondents (195/272) agreed that their pharmacist was an important source of information about generic medications. This is further supported by the 163 respondents (59.4%) who would accept the generic if their pharmacist simply offered it to them. The statement that received the greatest positive response on the survey was, "I trust my pharmacist and if he/she said a generic might not be as effective as the brand name, I would stick with the brand name." Eighty-nine percent of respondents (116/130) agreed with this statement. The present survey reaffirms that people in general trust their pharmacist and believe the information the pharmacist provides.

Opinions of Discretionary Generic Substitution

One feature of this survey that was different from previous studies was identifying specific categories of drugs to determine whether people would accept the generic product. Previous surveys treated the generic medication question as an absolute. That is, the surveys asked if people thought generics were as good as brand name medications or if the respondent would accept the generic product. The present survey asked about specific drug categories to determine if people would accept the generic version for some medications, but not others. Indeed, the results indicate that some people are less likely to accept generics for serious medical conditions such as diabetes, hypertension, or cancer. Respondents were also less likely to accept the generic for preventive drugs such as oral contraceptives. Over twice as many respondents were willing to accept generics for medications that give symptomatic relief, such as for pain, coughing, or cramping. This suggests people are willing to accept the less expensive product if the condition is not serious, but are less trustful of generics for more serious medical situations.

Another way to examine the generic issue is by cost. Some people might say they do not like generics, but would accept one if the cost savings was significant. The real question is what level of cost savings is significant? To

most of the respondents of this survey, the cost savings had to be $5.00 or more. This is a significant piece of information, because many managed care companies structure their copayment programs to encourage generic usage. Many programs show a differential of only a few dollars, such as $5.00 for brand name and $3.00 for generics. According to this survey, this differential is not enough to motivate people to use generics. Companies are going to have to show wider spreads between brand and generic copayments in order to motivate members to use more generic drugs.

Spearman Correlations

The Spearman correlation coefficients were moderately helpful in reviewing the data. Unfortunately, the relationships noted were weak ones and most were not statistically significant. It would appear that opinions are not strongly associated with a person's level of income or education. No correlation could be established between gender and generic attitude. There was a weak association related to age and generic opinions which was an inverse relationship. The survey sample was a fairly young group consisting of a large number of people between 20 and 30 years old. The Spearman coefficient apparently represented more people who were skeptical of generics in the older age groupings.

It is also apparent that people who ask for generics will accept them for a smaller cost savings. People who

responded that they do not usually ask if a generic is available were more likely to require a higher cost savings in the range of $5.00 or more in order to purchase a generic. Also, people who ask if a generic is available are more likely to accept one for any type of condition. The survey questions were intended to determine if a person's opinion of generics was absolute or dependent on the specific medication. If patients generally asked if a generic was available, they were more likely to accept the generic version for all three categories examined. This would seem to indicate that people who ask about generic availability trust these products irrespective of pharmacological class or treatment purpose.

Limitations of the Study

There were a few limitations to the study that might have prevented acquisition of better information. The first limitation was that only 32% of the people who were mailed a survey actually responded. A second mailing might have yielded a higher response rate.

A second limitation to the study was one additional demographic variable that could have been examined. That variable is the number of prescriptions the respondent's family has filled in a typical year. This question was in the original survey, but had to be deleted because of space constraints. In retrospect, this variable would have been good to study because people who must purchase numerous

prescriptions each year might pay closer attention to news reports about prescription medication. It would be interesting to include this variable in future studies to determine if a correlation exists.

This survey made the statement, "I trust my pharmacist and if he/she said a generic medication might not be as effective as the brand name, I would stick with the brand name." This statement received the highest agreement on the survey. In retrospect, it would have been enlightening to ask the reverse question, "If my pharmacist told me the generic medication would work as effectively as the brand name, I would purchase the generic." The data from this survey give every indication that the pharmacist has tremendous influence with the consumer. However, additional research could further substantiate that the pharmacist can reassure patients who must take the generic version because of their insurance program.

One further limitation to the study relates to the design of the question on the amount of money a respondent would need to save to purchase the generic product. The choices were $1.00, $2.00, $3.00, $4.00 or $5.00 or more. Because the majority of people answered $5.00 or more, it is difficult to determine how high the value needed to be in order to entice consumers to select a generic. In retrospect, this question would have yielded better data had it been left open with no choices.

Summary

This survey was initiated to study people's opinions of generic medication, review their knowledge of the generic drug scandal of 1989, and examine their opinions of their pharmacist in relation to generics. The results, which have been examined in detail, would indicate a much more positive perspective on generic medications than previous studies indicated. The trust people have in their pharmacists has been reaffirmed as it relates to information and influence on generics. As managed care programs give stronger incentives for people to use generic medication, it would appear many consumers will react positively. In the cases where generics are mandated, pharmacists are in a good position to give the information and support necessary to reassure the patient about these products.

References

1. Perri III M, Wolfgang A, and Jankel C. Georgia consumer's awareness and perceptions of generic drugs after the scandals. American Pharmacy 1990;(Oct):33-36.

2. Anonymous. Gallup survey reveals increased public concern about generic drug quality. Hospital Formulary 1990;(Mar):257-8.

3. Conlan M. After the storm: has the scandal shaken your confidence? Drug Topics 1991;(Jun)17:40-44.

APPENDIX

QUESTIONNAIRE AND COVER LETTER

SCRIP CARD

January 25, 1991

Dear Scrip Card Member,

Enclosed you will find a survey which asks questions about your opinions regarding generic medication and Scrip Card service. We have contracted with Steve Avey at the University of Utah College of Pharmacy to conduct and analyze this study. Your response is very important to us and the results will help us formulate policies regarding your prescription drug benefits in the future. This information may also have national implications as the results will be shared with other policy makers around the country.

The survey results are strictly confidential and your name will not be reported in any way that will identify you. Up in the right hand corner of the survey you will notice a number. This number will only be used to identify receipt of your survey so that you will not be contacted in the future and asked to fill out another one. There are no right or wrong answers on this survey. We simply want to know and understand how you feel about generic medications and your Scrip Card services.

After completing the survey, which should take only a few minutes, please place it in the envelope provided and drop it in a mail box. There is no postage needed. It is important that we obtain this information as soon as possible. We are asking that you return the survey by March 1, 1991.

This information is extremely important to us! We want to offer our members the best possible benefits at the most economical price, and our survey will help us develop programs that best meet your needs. Thank you for taking a few minutes out of your busy schedule to help us.

Sincerely,

Larry Madsen
President
Scrip Card

PRESCRIPTION PROCESSING/CONSULTING 875E 5180S. STE D MURRAY UTAH 84107 (801)268-3136 FAX(801)281-1333

A Survey of Scrip Card Members Regarding Generic Medication

Thank you for taking a few minutes to fill out our survey. The purpose of the survey is to gather information regarding your opinions about purchasing generic medications. As you know, generic medications contain the same active ingredient as brand name medications, but they may be made by a different company. For example, Tylenol , which is made by McNeil Labs contains Acetaminophen. Since the patent has expired, numerous companies have manufactured Acetaminophen tablets as a generic medication. This survey contains statements which you should read carefully. Using the code below this paragraph, circle the number which most closely represents your feelings about the statement. THERE ARE NO RIGHT OR WRONG ANSWERS. We simply want to understand how you feel about purchasing generic medication.

#1 = Strongly Disagree #2 = Disagree #3 = Neutral #4 = Agree #5 = Strongly Agree

	SD	D	N	A	SA
1. My prescription card (Scrip Card) is very important to me as a health care benefit.	1	2	3	4	5
2. When I have had to deal with Scrip Card directly, I have found them to be helpful and pleasant.	1	2	3	4	5
3. When I present my Scrip Card to the pharmacist with my prescription, I am usually greeted with a positive response.	1	2	3	4	5

4. The type of pharmacy I generally use is a _____ (circle one-specify if other)

Small Independant Chain Store Other _____

5. Some insurance companies demand that people purchase generic medications when they are available. It is important to me to be able to choose generics for myself.	1	2	3	4	5
6. In my opinion, generic medications are as effective as brand name medications.	1	2	3	4	5
7. I have actually used generic medications and have been satisfied with the results.	1	2	3	4	5
8. I trust the FDA (Food and Drug Administration). If generic medications pass FDA standards, they must be as good as brand name medications.	1	2	3	4	5
9. When I get a prescription filled, I usually ask if a generic is available.	1	2	3	4	5
10. My pharmacist is an important source of information to me regarding generic medications.	1	2	3	4	5
11. If the pharmacist asked me if I wanted to buy a generic medication in order to save money, I would do it.	1	2	3	4	5
12. In general I would NOT buy a generic medication for a condition such as diabetes, high blood pressure, or cancer.	1	2	3	4	5
13. In general I would NOT buy a generic medication for a condition such as pain, cramping or coughing.	1	2	3	4	5

	SD	D	N	A	SA
14. In general I would NOT buy a generic medication for a preventive purpose such as birth control pills.	1	2	3	4	5

15. In order for me to choose a generic I would need to save $_____.
(please circle the number which represents the money you would need to save.)

1 = $1.00 2 = $2.00 3 = $3.00 4 = $4.00 5 = $5.00 or more

16. Have you heard of any publicity regarding generic medication in the past few years? (circle one) yes no

IF YOU ANSWERED NO, PLEASE SKIP DOWN TO QUESTION 26. IF YOU ANSWERED YES CONTINUE WITH QUESTION 17.

17. The publicity I am familiar with, decreased my faith in the Food and Drug Administration (FDA).	1	2	3	4	5
18. The publicity decreased my faith in generic medication.	1	2	3	4	5
19. More recent publicity that I have heard has been favorable to the FDA and generic medication.	1	2	3	4	5
20. Although certain irregularities were found a few years ago at the FDA and at certain generic manufacturers, generics are as safe today as ever.	1	2	3	4	5
21. When I first heard the publicity about generic medications, I asked my pharmacist to explain what was happening.	1	2	3	4	5
22. Today, I feel confident in the FDA and trust their ability to regulate the generic drug industry.	1	2	3	4	5
23. Even though I may have heard positive reports about the FDA, I am still uneasy about taking generic medications.	1	2	3	4	5
24. I trust my pharmacist and if he/she said a generic medication might not be as effective as the brand name, I would stick with the brand name.	1	2	3	4	5
25. Today, I feel more confident in generic medication than ever before.	1	2	3	4	5

Could we get some information about you? Please circle the number of the item that best describes you.

26. My age category is: 1. 21 to 30 2. 31 to 40 3. 41 to 50 4. 51 to 60 5. 61 or over

27. I am a: 1. Female 2. Male

28. My level of education is: (please circle all that apply)
1. Attended high school 2. Graduated from high school 3. Attended college
4. Graduated from college 5. Attended graduate school 6. Other _____

29. The level of income for our family is: (annual income)
1. up to $15,000 2. $15,001 to $25,000 3. $25,001 to $35,000
4. $35,001 to $45,000 5. $45,001 to $55,000 6. $55,001 and above

30. Including yourself, how many dependants use your Scrip Card benefit? _____